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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,401	07/01/2003	Manabu Sato	239707US0	9350

22850 7590 08/09/2005

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EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,401

Applicant(s)

SATO ET AL.

Examiner

Susan E. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed May 27, 2005, has been received and entered. The Declaration of Mr. Manabu Sato has been received and considered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim 1, 3-5, and 7 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rendered indefinite by part (ii). Part (ii) is considered separate from part (i), thus it is not clear what active step is disclosed by the phrase, "by bringing the immobilized enzyme...". The phrasing implies that there is an effect obtained by bringing the immobilized enzyme in contact with a fatty acid, fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof. However, no effect is recited in part (ii). Thus, claims 3, 4, and 7 are rejected under 35 U.S.C. 112, second paragraph. It is suggested that applicant delete the word "by" to overcome this rejection.

Claim Rejections - 35 USC § 102

Claims 3, 4, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al. (EP 1,008,647).

EP '647 discloses preparation of an immobilized enzyme for esterification where the enzyme is immobilized on anion exchange resin without drying. The immobilized enzyme is treated with fat and/or oil which are the reaction substrates. See claims 1, 4, 6, and 7 on pages 7 and 8. Example 1 describes the immobilization of 10 g of lipase on 10 g of anion exchange resin, followed by treatment with 40 g of soybean oil (page 5, lines 26, 34, and 37). According to the applicants' specification, soybean oil may be used as a fatty acid triglyceride or fatty acid partial glyceride for the treatment of the immobilized enzyme (page 9, last paragraph). In EP '647, the quantity of this oil is 400% by weight based on the weight of the carrier, thus satisfying the weight limitation specified in claim 3. Similarly, Example 3 describes the immobilization of 10 g of lipase on 10 g of anion exchange resin, followed by its treatment with 100 g of aliphatic acid (a fatty acid) derived from soybean oil (pages 5 and 6, in particular, page 5, line 58, and page 6, lines 7-8, 14. Thus the fatty acid amount is 1000% by weight based on the weight of the carrier. Finally, the moisture content of the immobilized enzyme in the '647 invention is given as having a water content of 20% or more by weight (page 4, lines 35-37), thus satisfying the moisture content limitation indicated in claim 3.

All of applicant's argument has been fully considered but is not persuasive of error. Applicant alleges that '647 fails to disclose or suggest a process in which an immobilized enzyme in contact with an oil and/or fat is subject to dehydration. However, '647 points out a

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preferable embodiment wherein “the immobilized enzyme after immobilized by adsorption is deprived (or removed) of water sufficiently by a physical method and then brought into contact with the substrate to effect the esterification reaction” (page 4, lines 55-56), wherein the substrate includes fats and oils (page 4, lines 30-31). The resulting water content in the immobilized enzyme is “usually 20% or more by weight and preferably in the range of 40 to 60% by weight” (page 4, lines 56-58). Comparative Example 1 (page 6, paragraph [0047]) discloses the above embodiment, wherein the water content is reduced to about 2% by treating immobilized enzyme under reduced pressure, thus anticipating claim 7. While it is noted that this separate drying step does not proceed the step of contacting the immobilized enzyme with a fat/oil, in the order recited in claim 3 and its dependants, the claims under examination do not require that the steps are in a particular order.

Another preferred embodiment is disclosed which suggests a drying step following the step of contacting the immobilized enzyme with a fat/oil. ¶ 647 states that “after the lipolytic enzyme is immobilized by adsorption onto a carrier for immobilization, the initial esterification reaction is conducted by directly bringing the immobilized enzyme **without drying** into contact with the substrate, and removal of this excess water content in this initial esterification requires extra reaction time but can be effected in a considerably shorter time than the time for conventionally conducted drying of the immobilized enzyme” (page 5, lines 3-7, emphasis added). Moreover, “it is possible to use any method known in the public art, such as dehydration under reduced pressure...and dehydration using a dehydrating agent such as molecular sieves” (page 5, lines 14-16), thus anticipating claim 7.

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Since the prior art discloses a separate dehydration step, a holding of anticipation is clearly required.

Claims 3, 4, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimizu et al. (U.S. Pat. No. 6,716,610).

The applied reference has a common assignee and two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In the response filed on May 27, 2005, applicants note that EP 1,008,647, U.S. 6,716,610, and U.S. 2003/0096383 share common identification of inventors as well as priority claims to Japanese 10-346822 and 10-350920 and the disclosures therein are considered to be equivalent. Therefore, Shimizu et al. anticipates claims 3, 4, and 7. See discussion above.

Claims 3, 4, and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Shimizu et al. (U.S. 2003/0096383).

The '383 application discloses the same claim limitations as disclosed by the '610 and '647 patents. See discussion for '647. A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '647 in view of Shimizu et al. (U.S. Pat. No. 6,258,575) and Ruthven (Encyclopedia of Separation Technology, Vol. 2, John Wiley & Sons, Inc., 1997, page 1072).

As discussed above, EP '647 discloses a process of treating immobilized enzymes with fat/oil which is the reaction substrate. EP '647 does not expressly disclose that the fatty triglyceride, etc. is 800 to 5,000% by weight based on the weight of the carrier. Furthermore, it does not expressly disclose that the moisture content of the enzyme is 5% to 50% by weight based on the weight of the carrier, after contacting the immobilized enzyme with fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof.

However, Shimizu '575 discloses that 2000 g of soybean-squeezed oil is passed through a column holding 20 g of immobilized lipase. See Example 2, column 8, lines 25-36. The oil mixture is sent through the column multiple times (column 8, line 36 through column 9, line 7, in particular column 8, lines 59-62). The weight of the carrier, an anion exchange resin, may be

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estimated by performing a calculation using the dimensions of the column (column 8, lines 28-30) and the density range of exchange resin provided by Ruthven (page 1072, first paragraph under "Density and Specific Gravity"). A density of 700 g/L was used for the estimation, and the mass of resin was determined to be about 48 g. Therefore, the amount of soybean-squeezed oil used in Shimizu '575 was about 4100% by weight based on the weight of the carrier. This fits within the range recited in part (ii) of claim 1.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have increased the amount of fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof used for treating the immobilized enzyme as described in EP '647.

One of ordinary skill in the art would have been motivated to do this because it would have improved exposure of the immobilized enzyme to the reaction substrate. Furthermore, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the process would differ depending on the amount of fat employed.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that the moisture content of the immobilized enzyme after contacting with fat/oil is an amount that falls within the range of 5% to 50% by weight based on the weight of the carrier.

One of ordinary skill in the art would have been motivated to do this because '647 states that "after the lipolytic enzyme is immobilized by adsorption onto a carrier for immobilization, the initial esterification reaction is conducted by directly bringing the immobilized enzyme

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without drying into contact with the substrate, and removal of this excess water content in this initial esterification requires extra reaction time but can be effected in a considerably shorter time than the time for conventionally conducted drying of the immobilized enzyme” (page 5, lines 3-7, emphasis added). Since reduction of water content is desired, one of ordinary skill in the art would have been motivated to have ensured that the water content is 20% or more by weight, or 40 to 60% by weight, since this was the preferred water content range for the embodiment wherein the drying step proceeds enzyme immobilization (page 4, paragraph [0037]). It would have been applicable to any immobilized enzyme used for decomposing oil and fat, even when no active drying step is included in the process of treating immobilized enzyme. Moreover, the selection of the appropriate water content clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the immobilized enzyme on fat/oil decomposition would differ depending on the water content of the treated immobilized enzyme. A holding of obviousness is clearly required.

Claims 1, 3-5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,716,610 or U.S. 2003/0096383.

In the response filed on May 27, 2005, applicants note that EP 1,008,647, U.S. 6,716,610, and U.S. 2003/0096383 share common identification of inventors as well as priority claims to Japanese 10-346822 and 10-350920 and the disclosures therein are considered to be equivalent.

The ‘610 patent or ‘383 application each discloses a process where an enzyme for esterification of fats/oils is immobilized on a carrier without drying, followed by the treatment of the immobilized enzyme with the reaction substrate.

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However, they do not expressly disclose that the fatty triglyceride, etc. is 800 to 5,000% by weight based on the weight of the carrier. Furthermore, the references do not expressly disclose that the moisture content of the enzyme is 5% to 50% by weight based on the weight of the carrier, after contacting the immobilized enzyme with fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have varied the amount of fatty acid triglyceride, etc. used in the '610 patent or '383 application.

One of ordinary skill in the art would have been motivated to do this since, as stated above, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill. Although Example 3 in each of the references discloses the treatment of immobilized enzyme with a fatty acid (aliphatic acid) in the amount of 1000% by weight based on the weight of the carrier, one of ordinary skill in the art would have expected that this amount would have been suitable when the substrate is a fatty triglyceride, a fatty acid partial glyceride or mixtures thereof, instead of a fatty acid. Note that '610 points out that the substrate includes aliphatic acids (column 5, line 6), and that "for preparation of esters having a single aliphatic acid component, partial glycerides and/or triglycerides, these aliphatic acids can be used alone or may be used as a mixture of two or more type thereof" (column 5, lines 10-14). Thus, the aliphatic acids of Example 3 can be substituted with partial glycerides and triglycerides. Finally, the references do not disclose any upper limits for the amounts of fat/oil used to treat immobilized

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enzyme. Therefore, the reference does not suggest that the amount of fat/oil can not be in the weight range recited in claim 1.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that the moisture content of the immobilized enzyme after contacting with fat/oil is reduced to an amount that falls within the range of 5% to 50% by weight based on the weight of the carrier.

One of ordinary skill in the art would have been motivated to do this because '647 (essentially the same disclosure as '610 and '383) discloses that "after the lipolytic enzyme is immobilized by adsorption onto a carrier for immobilization, the initial esterification reaction is conducted by directly bringing the immobilized enzyme **without drying** into contact with the substrate, and removal of this excess water content in this initial esterification requires extra reaction time but can be effected in a considerably shorter time than the time for conventionally conducted drying of the immobilized enzyme" (page 5, lines 3-7, emphasis added). Since reduction of water content is desired, one of ordinary skill in the art would have been motivated to have ensured that the water content is 20% or more by weight, or 40 to 60% by weight, since this was the preferred water content range for the embodiment wherein the drying step proceeds enzyme immobilization (page 4, paragraph [0037]). It would have been applicable to any immobilized enzyme used for decomposing oil and fat, even when no active drying step is included in the process of treating immobilized enzyme. Moreover, the selection of the appropriate water content clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the immobilized

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enzyme on fat/oil decomposition would differ depending on the water content of the treated immobilized enzyme.

A holding of obviousness is clearly required.

Applicant's arguments filed May 27, 2005, have been fully considered but they are not persuasive. Though '575 and Ruthven do not disclose a separate dehydration step, they are cited in order to render the claims obvious by disclosing a method wherein immobilized enzyme is contacted with fat/oil in the amount of 800 to 5000% by weight based on the weight of said carrier. The artisan of ordinary skill viewing the '647, '575, and Ruthven references clearly would have considered applying the treatment steps and parameters disclosed in '575 in performing the methods of '647. Thus, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Additionally, applicant alleges that '647 fails to specifically suggest any amount of oil phase to contact with the immobilized enzyme. The examiner respectfully disagrees since '647 discloses that the reaction substrate for immobilized enzyme treatment includes oils (page 4, paragraph [0033]), such as soybean oil as used in Example 1 (page 5, line 37).

The Declaration under 37 C.F.R. 1.132 filed on May 27, 2005, has been received and considered. According to M.P.E.P. 716.07: "...Since in a patent it is presumed that a process if used by one skilled in the art will produce the product or result described therein, such

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the skill of the competent worker. The failures of experimenters who have no interest in succeeding should not be accorded great weight. In re Michalek, 162 F.2d 229, 74 USPQ 107 (CCPA 1947); In re Reid, 179 F.2d 998, 84 USPQ 478 (CCPA 1950).” Moreover, though the moisture content obtained by repeating the methods of Example 1 of ‘610 (thus ‘647) did not result in a moisture content of 5% to 50% by weight based on the weight of the carrier, it is respectfully pointed out that ‘647 indicates a preferred water content range (page 4, paragraph [0037]) within the ranges recited in claims 1 and 3. Though the results obtained by Mr. Manabu Sato using an oil amount of 400% by weight based on the weight of the carrier resulted in a moisture content above the recited ranges, it does not eliminate all possibilities that the invention rendered obvious by ‘647 would not have resulted in the recited moisture content. Further still, the Declaration only speaks to the case where 400% by weight of oil based on the weight of carrier is used, rather than all other amounts of oil that are rendered obvious by the above references. It is respectfully pointed out that the above rejections for claims 1, 3-5, and 7 are 103 rejections; thus contrary to the results obtained by Mr. Manabu Sato, the amounts of fatty acid triglyceride, etc. recited in the claims as amended are considered obvious as discussed in the above 103 rejections.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 5 are directed to an invention not patentably distinct from claims 1-4 of commonly assigned U.S. Pat. No. 6,716,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims recite the same basic steps as recited in the patented claims, to the extent that the limitations recited in the claims under examination are contained under the patented claims with the exception of the fat/carrier amount recited in claim 1. While the weight ranges of fatty acid, fatty acid triglyceride, etc. as recited in claim 1 had not been expressly recited in US '610, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned claims, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

In conclusion, claims 1 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,716,610. The claims are directed to an invention not patentably distinct from U.S. '610.

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan E. Fernandez
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sef



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PRIMARY EXAMINER